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Hiraku Murayama

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EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

11/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/635,716	Applicant(s) MURAYAMA ET AL.	
	Examiner EMILY M. LLOYD	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 28 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25-27, 29, 30 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's 2 July 2009 amendment. The Examiner acknowledges Applicant's amendments to claim 23, the cancellation of claim 24, and the addition of claim 35. Currently, claims 1-23 and 25-35 are pending, and claims 1-22, 28 and 31 are withdrawn from prosecution.

Information Disclosure Statement

2. Regarding Applicant's submission of the English abstract of WO 9801184 in place of the missing JP 2000-514326 abstract, the Examiner first notes that a "patent family" can entail many inventions; as such, it is unclear if the English abstract of the WO document would be the same as the English abstract of the JP document. The Examiner further notes that the IDS submitted 11 July 2008 was previously considered on 6 October 2008; as such, any further references, including those listed on previous IDSs but not in compliance with 37 CFR 1.98 at the time of their submission should be resubmitted in another IDS if Applicant would like them considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 23 claims "the cross-sectional area of the end face of the first end portion of the second wire being less than the cross-sectional area of the end face of the first end portion of the first wire at least after the welding." The Examiner notes that only Figure 1 of Applicant's specification shows a guidewire that meets this limitation. As such, claim 33 (which describes the small cross-sectional area portion 32 of Figures 5 and 6) and claim 34 (which describes the small cross-sectional area portion 32 of Figure 6) are considered new matter as they were not originally disclosed as being made from wires with different size end faces. Claim 32 also appears to claim Figures 5 and 6 in that all the comparisons made appear to be between end portions and not the end faces of end portions. See also the 112 2nd paragraph rejection of claim 32 below.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 25-27 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claims 25-27, it is unclear what limitations are presented in claim 25 by "the method of making a guide wire according to claim 24" as claim 24 was cancelled; claims 26 and 27 depend on claim 25 and thus the same cancelled limitation. For the purpose of examination, the Examiner has interpreted claim 25 as depending on claim 23.

9. Regarding claim 32, it is unclear what relationships Applicant is claiming. It is unclear if Applicant is claiming that the first end portion of the second wire has a cross-sectional area smaller than the cross-sectional area of the first end portion of the first wire, or if Applicant is claiming that the first end portion of the second wire has a cross-sectional area smaller than the cross-sectional area of the first end face of the first wire. Additionally, it is unclear whether Applicant is claiming that the first end portion of the second wire, the first end portion of the first wire, the first end face of the second wire, or another component possessed a flexural rigidity nearly equal to a flexural rigidity of the first end portion of the first wire.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 23, 25-27, 29, 30, 32 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Skujins et al. (US 6,918,882) as modified by Mortier et al. (US 5,372,144).

Regarding claim 23, Skujins et al. disclose a method of making a guide wire comprising: positioning a first wire (16) comprising a first end portion having an end face which possesses a cross-sectional area adjacent a second wire (14) comprising a first end portion having an end face which possesses a cross-sectional area so that the first

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end portion of the first wire is adjacent the first end portion of the second wire (the end portions are adjacent prior to welding to form the guidewire of Figure 4), the first end portion of the first wire being made from a material having an elastic modulus that is different from the elastic modulus of the material from which the first end portion of the second wire is made (Column 2 line 35-52); welding the first end portion of the first wire and the first end portion of the second wire to one another (Column 5, lines 50-67) without axial overlap (see Figure 4) to produce a guide wire having a welded portion.

Skujins et al. do not expressly disclose that the cross-sectional area of the end face of the first end portion of the second wire is less than the cross-sectional area of the end face of the first end portion of the first wire after welding. Mortier et al. teach a guide wire with the cross-sectional area of the end face of the first end portion of the second wire being less than the cross-sectional area of the end face of the first end portion of the first wire after manufacturing (the cross-sectional area of the end face of tapered segment 30 is less than the cross-sectional area of the end face of segment 34 Figures 8, 10 and 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such a change in cross-sectional area between different portions of a guidewire as taught by Mortier et al. in the invention of Skujins et al. as this would provide for a less expensive weld with larger tolerances (the wires of Skujins et al. would not have to be perfectly centered before welding as the grinding of Skujins et al. (Column 6 lines 1-7) would remove the exterior-most portion of the end of the second wire (to result in the transition/change in end face cross-sectional area of Mortier et al.)). Skujins et al. as modified by Mortier et al. also teach that the

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first end portion of the first wire is a proximal end portion of the first wire (Mortier et al. proximal portion of 34) and the first end portion of the second wire is a distal end portion of the second wire (Mortier et al. distal end of 30).

Regarding claim 25, Skujins et al. as modified by Mortier et al. teach the method of claim 23, wherein the elastic modulus of the distal end portion of the second wire is greater than the elastic modulus of the proximal end portion of the first wire (Skujins et al. Column 2 line 35-52).

Regarding claims 26 and 29, Skujins et al. as modified by Mortier et al. teach the methods of claims 23 and 25, further comprising reducing the cross-sectional area of the distal end portion of the second wire after the proximal end portion of the first wire and the distal end portion of the second wire are welded to one another (Skujins et al. Column 6 lines 1-7, as combined with the transition of Mortier et al.).

Regarding claims 27 and 30, Skujins et al. as modified by Mortier et al. teach the methods of claims 25 and 29, wherein the cross-sectional area of the distal end portion of the second wire is reduced by grinding (Skujins et al. Column 6 lines 1-7, as combined with the transition of Mortier et al.).

Regarding claim 32, Skujins et al. as modified by Mortier et al. teach the method of claim 23, wherein a flexural rigidity of the distal end of said second wire is nearly equal to that of the proximal end of the first wire (Skujins et al. at 16).

Regarding claim 35, Skujins et al. disclose a method of making a guide wire comprising: positioning a first wire (16) comprising a proximal end portion having an end face which possesses a cross-sectional area adjacent a second wire (14) comprising a

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distal end portion having an end face which possesses a cross-sectional area so that the proximal end portion of the first wire is adjacent the distal end portion of the second wire (the end portions are adjacent prior to welding to form the guidewire of Figure 4), the proximal end portion of the first wire being made from a material having an elastic modulus that is different from the elastic modulus of the material from which the distal end portion of the second wire is made (Column 2 line 35-52); welding the proximal end portion of the first wire and the second end portion of the second wire to one another (Column 5, lines 50-67) without axial overlap (see Figure 4) to produce a guide wire having a welded portion.

Skujins et al. do not expressly teach that the cross-sectional area of the distal end portion in a vicinity of the welded portion of the second wire is less than the cross-sectional area of the end face of the proximal end portion at least after the welding. Mortier et al. teach a guide wire with the cross-sectional area of the distal end portion in a vicinity of the welded portion of the second wire is less than the cross-sectional area of the end face of the proximal end portion at least after the welding (the cross-sectional area of the distal end portion in a vicinity of the welded portion of tapered segment 30 is less than the cross-sectional area of the end face of segment 34 Figures 8, 10 and 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such a change in cross-sectional area between different portions of a guidewire as taught by Mortier et al. in the invention of Skujins et al. as this would provide for a less expensive weld with larger tolerances (the wires of Skujins et al. would not have to be perfectly centered before welding as the grinding of

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Skujins et al. (Column 6 lines 1-7) would remove the exterior-most portion of the end of the second wire (to result in the transition/change in end face cross-sectional area of Mortier et al.)).

14. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skujins et al. as modified by United States Patent 6001068 (Uchino et al.).

Regarding claim 35, Skujins et al. disclose a method of making a guide wire comprising: positioning a first wire (16) comprising a proximal end portion having an end face which possesses a cross-sectional area adjacent a second wire (14) comprising a distal end portion having an end face which possesses a cross-sectional area so that the proximal end portion of the first wire is adjacent the distal end portion of the second wire (the end portions are adjacent prior to welding to form the guidewire of Figure 4), the proximal end portion of the first wire being made from a material having an elastic modulus that is different from the elastic modulus of the material from which the distal end portion of the second wire is made (Column 2 line 35-52); welding the proximal end portion of the first wire and the second end portion of the second wire to one another (Column 5, lines 50-67) without axial overlap (see Figure 4) to produce a guide wire having a welded portion.

Skujins et al. do not expressly teach that the cross-sectional area of the distal end portion in a vicinity of the welded portion of the second wire is less than the cross-sectional area of the end face of the proximal end portion at least after the welding.

Uchino et al. teach a welded portion 69 on the proximal side of the boundary 68 of the

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two wires. The cross-sectional area of the distal end portion in a vicinity of the welded portion of the second wire (the cross-sectional area of 62 at the deepest portion of weld 69 Figure 14) is less than the cross-sectional area of the end face of the proximal end portion of the first wire (cross-sectional area of 61 at boundary 68 Figure 14). It would have been obvious to one having ordinary skill in the art at the time of invention to have spot welded the connector of Skujins et al. in the manner taught by Uchino et al. in order to achieve the predictable result of adhering a connector to two wires.

15. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skujins et al. as modified by Mortier et al. as applied to claims 23, 25-27, 29, 30, 32 and 35 above, and further in view of United States Patent 6001068 (Uchino et al.).

Regarding claims 33 and 34, Skujins et al. as modified by Mortier et al. teach the method of claim 23. Skujins et al. as modified by Mortier et al. do not expressly teach the claimed first, second and third portions.

Uchino et al. teach a welded portion 69 on the proximal side of the boundary 68 of the two wires. Uchino et al. teach a first portion (see portion of 62 immediately to the right of 63 in Figure 14) gradually reduced in the direction toward the distal end of said guidewire. As shown in Figure 14, the welded portion 69 creates a second portion of the wire having an outer diameter gradually increased in the direction toward the distal end of the wire (portion of 62 coinciding with the left/distal half of welded portion 69, Figure 14). Uchino also teaches a third portion having nearly constant outer diameter

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between the other portions (portion of 62 between the proximal end of 63 and the proximal end of 69 in Figure 14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have spot welded the connector of Skujins et al. as modified by Mortier et al. in the manner taught by Uchino to obtain the first, second and third portions as set forth in claims 33 and 34 in order to achieve the predictable result of adhering a connector to two wires.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 23-25 and 35 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 and 23 of copending Application No. 11/797328. This is

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a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the method of making the guidewire of this application claim 35 would produce the guidewire claimed in Application 11/797328 claim 1, and the method of making the guidewire of this application claims 23-25 would produce the guidewire claimed in Application 11/797328 claim 23.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

18. Applicant's arguments filed 2 July 2009 have been fully considered but they are not persuasive.

19. Regarding Applicant's arguments regarding the IDS submitted 11 July 2008, see the Information Disclosure Statement section above.

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20. Regarding Applicant's argument that the 35 USC 112 issues raised in the prior Office Action are addressed by the claim amendments, the Examiner notes that only a portion of these were addressed. Those not addressed are repeated above.

21. Regarding Applicant's argument regarding the potential cross-sectional area of "ribbon or segment 34" of Mortier et al., the Examiner notes that the entire Mortier et al. reference refers to 34 as a "ribbon or segment", including Figure 7, where segment or ribbon 34 clearly fits into central bore 80, and other figures where, according to Applicant's logic, the segment or ribbon 34 would be round. The Examiner also notes that Column 5 lines 68-Column 6 line 1 states "formable distal segment 34 having dimensions substantially smaller than corresponding dimensions of the segment 26" and Column 5 lines 49-50 state "The segment 26 has a diameter..."; in order for distal segment 34 to have "corresponding dimensions" to a circular cross section, it would have to be circular. It appears that Mortier et al. teach that 34 can be circular or rectangular in cross-section. The Examiner also notes that "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments" (MPEP 2123 I). While Column 6 lines 2-4 disclose a preferable embodiment, the entirety of the reference teaches that the segment 34 could also be circular in cross-section. The Examiner notes that, with a circular cross section for 34, Mortier et al. teach a distal end face of a proximal portion 30 having a smaller cross section than that of the proximal end face of a distal portion 34.

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22. The Examiner further notes that the drawings of Mortier et al. were not relied on as being to scale; instead, the drawings are relies on for what they reasonably teach one of ordinary skill in the art. The drawings clearly show the proximal end of 34 as larger than the distal end of 30. See MPEP 2125. Further, with both 34 and 30 having circular cross-sectional areas, any end face having a larger diameter than another end face will also have a larger cross-sectional area than the other end face.

23. The Examiner further notes that the attached drawings, while showing the final product of claim 35, do not provide support for Applicant's claims 32-34 which describe the first, second and third portions shown in the provided Figures 5 and 6 of Applicant's specification but do not have "the cross-sectional area of the end face of the first end portion of the second wire being less than the cross-sectional area of the end face of the first end portion of the first wire at least after the welding" as required by claim 23.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
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/EML/

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736